

**REMARKS**

Claims 25-33 are pending.

**Claim Rejections of Claims 25-33 under 35 U.S.C. 101**

The Examiner cites a statutory type 35 U.S.C. 101 double patenting rejection based on claims 25-33 of this application which conflict with claims 25-33 of application number 10/293,175.

In response, Applicants respectfully submit that the claims entered as a provisional amendment for 10/293,175 have been mistakenly entered. This matter is in the process of being resolved by Humera N. Sheikh, Primary Examiner of Art Unit 1615.

**Yang: Rejection of Claims 25-33 under 35 USC §103(a)**

The Examiner has rejected claims 25-33 under 35 USC § 103(a) as being unpatentable over Yang et al. (WO 01/01890 A1) ("Yang"). Applicants respectfully disagree.

Claim 25 recites "adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material." Claim 25 further recites "solidifying the coating material to a film layer wherein the film layer includes the polymeric particles containing the therapeutic substance." Yang fail to teach or suggest the above limitations of claim 25.

Yang disclose a "surface treatment" that is accomplished through "either dipping or spraying process." (p. 7, lines 18-20, Yang) In either process, "a solvent carrier" incorporates "the therapeutic agent within the polymer matrix." (p. 7, lines 19-20, Yang) Yang state that the "applied mixture preferably comprises a solvent, a polymer, and a therapeutic agent, with subsequent evaporation of the solvent to leave a polymeric coating." (p. 7, lines 20-23, Yang)

With respect to the first limitation recited above, Yang do not teach, expressly or inherently, adding polymeric particles containing a therapeutic substance to a coating material. Even if polymer particles were added to the "solvent carrier" to form a coating

mixture in Yang, there is no teaching or suggestion in Yang that such particles contain a therapeutic agent.

With respect to the second limitation, there is no teaching or suggestion in Yang the polymeric coating that is formed includes polymeric particles containing a therapeutic substance. In particular, there is no teaching or suggestion upon evaporation of the applied mixture of solvent, polymer, and a therapeutic agent results in a coating including polymeric particles containing the therapeutic agent. Although Yang teaches that active agent can be dispersed in the polymer of a coating, there is no express or inherent teaching that the dispersed active agent is within polymeric particles. Additionally, although Yang teaches that the coating can include a blend of first and second co-polymers, there is no teaching or suggestion that the blend includes particles of one polymer dispersed within the other.

Furthermore, the Examiner has provided no motivation for modifying the teachings of Yang so that it teaches the above-mentioned claim limitations. MPEP 2143 states that one of the requirements of a prima facie case of obviousness is that “there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Another criteria for a prima facie case is that the combined references teach or a modified prior art reference teaches or suggests all claim limitations. MPEP 2143.

The Examiner states that “given the explicit teachings of Yang et al., the instant invention, when taken as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.” The Examiner states a conclusion without providing any support or argument for meeting the requirements stated above for a prima facie case of obviousness. As indicated above, the “explicit teachings” of Yang do not teach all the claim limitations. Furthermore, the Examiner has not provided a suggestion or motivation contained either in another reference(s) or in the knowledge generally available to one of ordinary skill in the art to modify Yang so that it teaches the above-mentioned claim limitations. Therefore, the Examiner’s remarks do not meet either of the requirements for a prima facie case of obviousness above.

With respect to Examiner's remark, that "the prior art teaches a similar method of coating stents," Applicants have clearly demonstrated that Yang does not all the elements of Applicants method claim 25. Even if Yang's method is "similar" to Applicants' method, "similar" is not a criteria for prima facie case of obviousness. The criteria indicated above is that the modified prior art reference must teach all the claim limitations.

Since the Examiner has failed to establish a prima facie case of obviousness, claim 25 is allowable. Claims 26-33 depend from claim 25 and are allowable for at least the same reason that claim 25 is allowable. Applicant respectfully requests removal of the rejections.

Additionally, at least dependent claim 31 is independently patentable. The Examiner states that "Yang et al. employs similar polymeric materials as utilized by Applicant, and thus the polymeric particles (of Yang et al.) would have similar characteristics and impart similar effects, as the polymeric materials of the instant invention, thus including a 'hydrogel consistency'." Even if Yang disclose polymeric particles (which it does not) and even if Yang employs similar polymeric materials as Applicant, the methods and materials employed by Yang would not necessarily result in a hydrogel consistency. As disclosed by Applicant, a hydrogel consistency depends on both materials and the manner of processing, e.g., dipping followed by spraying as disclosed on p. 22, lines 22-32 of Applicants' specification. Yang do not disclose such a technique and the Examiner has not shown that the methods of Yang would result in a hydrogel consistency, other than a conclusory statement with no support.

**Berg: Rejection of Claims 25-32 under 35 USC §103(a)**

The Examiner has rejected claims 24-32 under 35 USC § 103(a) as being unpatentable over Berg et al. (U.S. Patent No. 5,464,650) ("Berg"). Applicants respectfully disagree.

The Examiner states that Berg "teach a drug-containing expandable stent and method for making an intravascular stent by applying to the body of a stent solution, which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance

dispersed in the solvent and then evaporating the solvent.” The Examiner further states that “the method can be applied by immersing the stent into the solution or by spraying the solution onto the stent (col. 2, lines 40-44). Processes for preparing the coated stent are also disclosed on column 3, line 52 - col. 4, line 34, wherein it is taught that a solution, which includes a solvent, polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared.”

Berg teach preparing a solution with a “polymer dissolved in a solvent” (col. 3, line 54), applying the solution to a stent, and then allowing the solution to evaporate. (col. 4, lines 19-20).

With respect to the first limitation recited above, Berg do not teach, expressly or inherently, adding polymeric particles containing a therapeutic substance to a coating material. Even if polymeric particles were added to the “solvent” to form the coating solution in Berg, there is no teaching or suggestion in Berg that such particles contain a therapeutic agent. With respect to the second limitation, there is no teaching or suggestion in Berg that the polymeric coating that is formed includes polymeric particles containing a therapeutic substance.

Berg do teach coating a stent with a solution containing solvent with a therapeutic substance “dispersed in fine particles.” (col. 3, line 64) In addition, Example 2 of Berg teaches dipping a stent in a “solution with suspended particles of dexamethasone.” (col. 5, lines 60-61) However, there is no indication by Berg or the Examiner that a coating with polymeric particles containing therapeutic agent is formed. Thus, there is no express or inherent teaching or suggestion that the dispersed therapeutic agent is within polymer particles.

As with Yang, the Examiner states a conclusion of a prima facie case of obvious without providing any support or argument for it. The “explicit teachings” of Berg do not teach all the claim limitations. Furthermore, the Examiner has provided no motivation or suggestion to modify Berg so that it teaches the above-mentioned claim limitations.

Since the Examiner has failed to establish a prima facie case of obviousness, claim 25 is allowable. Claims 26-32 depends from claim 25 and are allowable for at least

the same reason that claim 25 is allowable. Applicant respectfully requests removal of the rejections.

Additionally, at least dependent claim 31 is independently patentable. As indicated above, a "hydrogel consistency" depends on the type of materials and manner of processing. Berg do not disclose such a technique and the Examiner has not shown that the methods of Berg would result in a hydrogel consistency, other than a conclusory statement with no support.

*Conclusion*

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

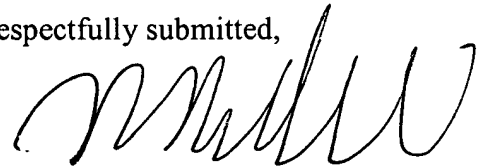
Should the Examiner have any questions regarding this communication, the Examiner is invited to contact the undersigned at the telephone number shown below.

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Respectfully submitted,



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